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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,674	11/01/2006	Reza Eivaskhani	CCS-5001-USPCT1	3640
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PHILIP S. JOHNSON			DICKINSON, PAUL W	
JOHNSON & JOHNSON				
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			12/17/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/538,674	EIVASKHANI ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	PAUL DICKINSON	1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 September 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3 and 6-14 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1, 3, 6-14 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Applicant's arguments, filed 9/26/2008, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 103***

The rejection of Claims 1, 3, and 6-13 under 35 U.S.C. 103(a) as being unpatentable over US 20050158385 ('385) is maintained.

Applicant argues that '385 does not teach or suggest cylindrical layers, as presently claimed. Applicant argues that '385 does not teach or suggest the desirability of separating the hygroscopic gum material from the moisture sensitive active ingredient as required in the instant invention. Applicant argues that '385 does not teach or disclose the compression of pre-shaped layers, but rather teach the simultaneous coating of a pre-shaped core.

Applicant's arguments have been fully considered but are not found persuasive.

Regarding the cylindrical layers, '385 explicitly states that the dosage form (including the core, middle layer, and outershell) may be cross-sectional shapes such as elliptical or rounded rectangular (see paragraph 19). "Circular cross-section" shapes are preferred, which suggests cylindrical shapes (see paragraph 83; Figure 1).

Applicant references Figure 2 of '385 for support that the layers must be spherical, but this Figure is a cross-section of dosage form, and by its circular shape implies that the overall dosage form is cylindrical (see paragraph 13; Figure 1).

Regarding the desirability of separating the hygroscopic gum material from the moisture sensitive active ingredient, while '385 does not disclose a specific example of this embodiment, such an embodiment is taught by the invention as one means of affording a multi-layered tablet with tunable dosage strength. That '385 teaches additional components in the overlay and core does not distinguish the invention of '385 from the present invention. The instant claims recite open language to describe the contents of the layers, and they are also open to such additional components.

Regarding the compression of pre-shaped layers, the term "pre-shaped" as recited in the instant claims is a broad term, and is interpreted to mean that the layers have some shape prior to the compression step. Regarding the compression step, '385 teaches that once the layers are placed (pre-shaped), the multi-layered strand should then be shaped into the desired dosage form, such as shaping into a tablet (see paragraph 87). In the examples, they are processed into tablets by an embedded cutting roll (a compressing apparatus) (see Examples 1-3).

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites “wherein at least one layer contains from about 30% to about 90% or from about 50% to about 80% of hygroscopic gum material”. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present case, claim 14 recites the broad recitation “from about 30% to about 90%”, and the claim also recites “from about 50% to about 80%” which is the narrower statement of the range/limitation.

Furthermore, it is unclear if the disclosed percents are weight or volume percents.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 20050158385 (hereafter '385). '385 discloses multi-layered tablets comprising three layers, namely, a core, a middle layer, and an outershell, wherein an effective amount of

a pharmaceutically active compound is present in any one of the three layers, and a thermoplastic polymer may be present in any one of the three layers, and the pharmaceutical active compound and thermoplastic polymer may be in different layers (see abstract; ¶1, 9-10, 16-23; Figure 2; Claims 1, 8, 10, 12, and 15). An exemplified pharmaceutically active compound is 2,3:4,5-bis-O-(1-methylethyldiene)-beta-D-fructopyranose sulfamate (topiramate) (see ¶ 37; Example 3). Preferred thermoplastic polymers include polyethylene glycol, hydroxypropyl methylcellulose and xanthan gum (see ¶ 23; Claim 15). In Example 3, the thermoplastic polymer polyethylene glycol is present in the middle layer in 83% by weight (calculated from  $(50 + 200)/(50 + 50 + 200) \times 100\%$ ). '385 explicitly states that the dosage form (including the core, middle layer, and outershell) may be cross-sectional shapes such as elliptical or rounded rectangular (see paragraph 19). “Circular cross-section” shapes are preferred, which suggests cylindrical shapes (see paragraph 83; Figures 1 and 2). The multi-layered tablets are compressed by using an embedded cutting roll (see Examples 1-3). The multi-layered tablets have several advantages over other tablet formulations, including tunable dosage strength (see abstract; ¶ 9-10)

‘385 fails to disclose a specific combination or example of a multi-layered tablet comprising topiramate and xanthan gum.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to prepare a multi-layered tablet comprising topiramate and xanthan gum wherein the two compounds are not in the same layer, with a reasonable

expectation of success, as doing so is taught by '385 as one embodiment that affords a multi-layered tablet with tunable dosage strength.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson  
Examiner  
AU 1618

December 13, 2008